DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 24 2009

Re: Neupro Transdermal System
Docket No.: FDA-2007-E-0048

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,884,434, filed by Schwarz Pharma Limited, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Neupro Transdermal System (rotigotine), the human drug product claimed by the patent.

The total length of the regulatory review period for Neupro Transdermal System (rotigotine) is 4,367 days. Of this time, 3,535 days occurred during the testing phase and 832 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 27, 1995.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 27, 1995.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: January 28, 2005.

   The applicant claims January 19, 2005, as the date the new drug application (NDA) for Neupro Transdermal System (NDA 21-829) was initially submitted. However, FDA records indicate that NDA 21-829 was initially submitted on January 28, 2005, the date of receipt by the Agency of a resubmission following a refusal to file.

3. The date the application was approved: May 9, 2007.

   FDA has verified the applicant's claim that NDA 21-829 was approved on May 9, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: J. Timothy Keane
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